

REMARKS

Applicants thank the Examiner for taking time on January 7, 2005, to discuss the outstanding Office Action. Reconsideration of the rejections set forth in the Office Action dated July 13, 2004, is respectfully requested. Applicants have amended claim 28 to expedite prosecution. Support for the amended claim is found in the specification at, e.g. page 3, line 7 – page 4, line 9. Therefore, this amendment is made without introducing new matter.

The Examiner rejected claims 28 and 30-31 under 35 U.S.C. § 112 as allegedly failing to enable persons skilled with in the art to make or use the invention commensurate in scope with these claims. In particular, the examiner has taken the position that the open ended ranges in claim 28 are indefinite because, they do not “reasonably provide enablement for a composition comprising an active ingredient comprising the particular parts of ions as Instantly claimed.” The examiner further argues that even a composition of “a plurality of solids, say 100, would still require that the ions be present in a particular ratio simply due to the chemical nature of the ions listed in the claims.” Therefore, according to the examiner, the contention that “Each of [the listed] ingredients is a cation and its contribution is determined on this basis, not on the basis of the weight of any counterions which may be in the composition” is inconclusive.

This argument is in error because open ended numerical ranges are not per-se indefinite. *See* MPEP § 2173.05(c)(II) Open-Ended Numerical Ranges. The MPEP explains that these ranges must be carefully analyzed for ambiguity, such as where an “at least” requirement for an ingredient of a composition cannot be satisfied given the minimum requirements of other ingredients, but that a claimed composition with a set of ranges that might in theory have a content greater than 100% are not per-se indefinite. Moreover, MPEP § 2173.05(c) adopts the holding of the Court of Customs and

Patent Appeals in *In re Kroekel* that “a rejection based on indefiniteness cannot stand simply because the proportions actually recited in the claims may be read in theory to include compositions that are in fact impossible to formulate.” *In re Kroekel*, 504 F.2d 1143, 1146 (CCPA 1974). Here, the court noted that where the requirements of the claims are clear such that each of the designated substances must be present and the amount of each substance must fall somewhere within the specified range, it could readily be ascertained whether a given composition would or would not infringe. Accordingly, the court held that despite the fact that the claims for the composition could in theory be read to include compositions with a content greater than 100%, they were not indefinite. *Id.*

Thus, the examiners objection that claim 28 is indefinite because the maximum ranges of ions listed could not theoretically be present given the presence of chemically required counterions is in error. Furthermore, applicant notes that the same claim language regarding the range of components by weight of inorganic solids for a therapeutic composition was previously approved by the Patent Office in claims 1 and 5 of U.S. Patent No. 6,149,947 (the ‘947 patent). The present application claims priority to the ‘947 patent. Therefore, the rejection of claims 28 and 30-31 under 35 U.S.C. § 112 should be withdrawn.

CONCLUSION

Because open ended numerical ranges are permissible according to MPEP § 2173.05(c) and because the claim language has previously been approved by the U.S. Patent and Trademark Office, withdrawal of the rejection of claims 28 and 30-31 under 35 U.S.C. § 112, second paragraph as being indefinite is respectfully requested. Applicants respectfully submit that the claims are now in

condition for allowance. Applicants invite the Examiner to telephone the undersigned representative if the Examiner believes that a telephonic interview would advance this case to allowance or if any clarifications are necessary.

Respectfully submitted,

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